REMARKS

Applicants request reconsideration of this application in view of the foregoing amendments and the following remarks.

Claims 69-84 are newly added and pending in this application, with claims 69, 73, 76, 79, 80 and 81 being independent. Claims 1-68 have been cancelled without prejudice to or disclaimer of the subject matter recited therein.

At the outset, Applicants would like to thank the Examiner for the courtesies extended in granting an interview and meeting with Applicants' representatives with regards to this application on March 8, 2005. At that time, the rejections set forth in the Office Action dated September 27, 2004 were discussed and possible further claim amendments were explored. Applicants present the claim amendments provided herein taking full consideration of the Examiner's comments during the interview.

Claim 69 recites a method of administering a pharmaceutical composition, wherein the method comprises: administering the pharmaceutical composition, comprising desloratadine and a suitable, inert pharmaceutically acceptable carrier or diluent, to target a pharmacokinetic (pK) profile for desloratadine comprising an arithmetic or geometric mean steady state maximum plasma concentration (C_{max}) of desloratadine of about 4 ng/mL, and an arithmetic or geometric mean time to maximum plasma concentration (T_{max}) of desloratadine of about 3 hours post dose.

Claim 73 recites a method of administering a pharmaceutical composition, comprising: administering the pharmaceutical composition, comprising desloratadine and a suitable, inert pharmaceutically acceptable carrier or diluent, once a day for about 10 days, wherein said administering is carried out to target a pharmacokinetic (pK) profile comprising an arithmetic or geometric mean steady state maximum plasma concentration (C_{max}) of desloratadine of about 4 ng/mL, and an arithmetic or geometric mean time to maximum plasma concentration (T_{max}) of desloratadine of about 3 hours post dose.

Claim 76 recites a method of administering a pharmaceutical composition comprising: administering the pharmaceutical composition, comprising desloratadine and a suitable, inert pharmaceutically acceptable carrier or diluent, for a period of time to target the establishment of a steady-state pharmacokinetic (pK) profile in the

bloodstream of a patient comprising an arithmetic or geometric mean steady state maximum plasma concentration (C_{max}) of desloratadine of about 4 ng/mL, and an arithmetic or geometric mean time to maximum plasma concentration (T_{max}) of desloratadine of about 3 hours post dose.

Claim 79 recites a method of achieving a pharmacokinetic (pK) profile of desloratadine that is safe and effective for treating nasal and non-nasal symptoms of seasonal and perennial allergic rhinitis and for treating symptoms of chronic idiopathic urticaria in a human 12 years or older, comprising: administering a dosage form comprising desloratadine and a suitable, inert pharmaceutically acceptable carrier or diluent, wherein said administering is carried out to target the pK profile and wherein the pK profile comprises an arithmetic or geometric mean steady state maximum plasma concentration (C_{max}) of desloratadine of about 4 ng/mL, and an arithmetic or geometric mean time to maximum plasma concentration (T_{max}) of desloratadine of about 3 hours post dose.

Claim 80 recites a method of treating nasal and non-nasal symptoms of seasonal and perennial allergic rhinitis in a human of 12 years and older comprising: administering a dosage form comprising desloratadine and a suitable, inert pharmaceutically acceptable carrier or diluent, wherein said administering is carried out to target a pharmacokinetic (pK) profile that is safe and effective for treating the allergic rhinitis symptoms, and wherein the pK profile comprises an arithmetic or geometric mean steady state maximum plasma concentration (C_{max}) of desloratadine of about 4 ng/mL, and an arithmetic or geometric mean time to maximum plasma concentration (T_{max}) of desloratadine of about 3 hours post dose.

Finally, claim 81 recites a method of treating symptoms of chronic idiopathic urticaria in a human of 12 years and older comprising: administering a dosage form comprising desloratadine and a suitable, inert pharmaceutically acceptable carrier or diluent, wherein said administering is carried out to target a pharmacokinetic (pK) profile that is safe and effective for treating the chronic idiopathic urticaria symptoms, and wherein the pK profile comprises an arithmetic or geometric mean steady state maximum plasma concentration (C_{max}) of desloratadine of about 4 ng/mL, and an arithmetic or geometric mean time to maximum plasma concentration (T_{max}) of desloratadine of about 3 hours post dose.

The term "about" as recited in the newly added claims is used by Applicants to mean the value includes that range of values (i.e., 80%-125%) that is considered to be bioequivalent for a systematically absorbed formulation.

Support for each of the newly added claims is provided in the specification. For example, support for the claims can be found in the specification at page 5, lines 5-13; page 7, lines 1-2; page 7, line 23 to page 8, line 8; page 20 (i.e., Table 2); and page 29, line 16 to page 30, line 10. Accordingly, Applicants believe that no new matter has been added by these claim amendments.

1. In the Office Action dated September 27, 2004, claims 16-20, 22-25, 27-39, 41-46, 48, 49, 51-60 and 63-68 have been rejected under 35 U.S.C § 103(a) as unpatentable over U.S. Patent No. 6,100,274 to Kou, in view of U.S. Patent No. 5,502,080 to Hitzig and U.S. Patent No. 5,698,558 to Gray.

Given that all of the rejected claims have been cancelled, without prejudice to or disclaimer of the subject matter recited therein, Applicants submit that this rejection set forth in the Office Action is rendered moot. Moreover, Applicants respectfully traverse this rejection in view of the following remarks, to the extent that it is deemed relevant to newly added claims 69 to 84.

First, according to Applicants' analysis, the rejection under 35 U.S.C § 103(a) is not proper at least because Applicants believe that the Kou patent does not constitute prior art as against this application. *See* MPEP § 2141.01. Both the subject matter of the Kou patent and the claimed invention in this application were, at the time the invention was made, owned by the same person, namely, Schering Corporation or subject to an obligation of assignment to Schering Corporation. Consequently, pursuant to 35 U.S.C § 103(c), the Kou patent cannot properly form the basis of a rejection under 35 U.S.C § 103(a) by qualifying as prior art under any of 35 U.S.C §§ 102(e), (f) or (g). Moreover, the February 3, 2000 priority date for the present application is prior to the August 8, 2000 publication date of the Kou patent. It is believed that the subject matter of the currently pending claims is fully supported by the provisional application to which the current application claims benefit. Accordingly, the Kou patent does not qualify as prior art under any of 35 U.S.C §§ 102(a), (b), (c) or (d).

Applicants do not believe that the Hitzig or Gray patents provide the additional elements in Applicants' claimed invention that are missing in the Kou patent.

According to Applicants' understanding, the Gray patent discloses methods for utilizing optically pure (–) cetirizine for the treatment of seasonal and perennial allergic rhinitis and chronic idiopathic urticaria in humans while avoiding the concomitant liability of adverse effects associated with the racemic mixture of cetirizine.

Also, according to Applicants' understanding, the Hitzig patent teaches treating allergic conditions, such as rhinitis or urticaria, and mitigating or resolving allergic symptoms by administering a dopamine agonist such as fenfluramine and/or 5-hydroxytriptophan, administered concurrently or in association with a serotonin agonist such as phentermine.

Applicants submit that it is not proper to combine the Hitzig or Gray patents with the Kou patent at least because each of these patents is directed to different chemical entities from desloratadine. Accordingly, a rejection under 35 U.S.C § 103(a) over the Kou patent in view of the Hitzig and Gray patents is not appropriate with respect to the present claims.

2. The Office Action also rejected previously pending (now cancelled) claims 16-20, 22-25, 27-39, 41-46, 48, 49, 51-60 and 63-68 under the judicially created doctrine of obviousness-type double patenting rejection as unpatentable over claims 3 and 15 of U.S. Patent No. 4,659,716 to Villani et al. in view of Hitzig and Gray. Applicants submit that this rejection is now moot and should be withdrawn, given that the rejected claims have been canceled.

Applicants further traverse this rejection to the extent that it is deemed applicable to the currently pending claims. Claim 3 of the Villani et al. patent recites a compound having a specified structural formula, which is desloratadine, or a pharmaceutically acceptable salt thereof. Claim 15 of Villani, et al. teaches a method of treating allergic reactions in a mammal which comprises administering to said mammal an anti-allergic effective amount of a compound as defined in claim 3.

However, neither of these claims recites nor renders obvious Applicants' presently claimed invention. For example, the Villani, et al claims do not recite targeting a pharmacokinetic (pK) profile for desloratadine comprising an arithmetic or geometric

mean steady state maximum plasma concentration (C_{max}) of desloratadine of about 4 ng/mL, and an arithmetic or geometric mean time to maximum plasma concentration (T_{max}) of desloratadine of about 3 hours post dose, as variously claimed in independent claims 69, 73, 76, 79, 80 and 81. The claims of Villani, et al. do not recite a method of administering a pharmaceutical composition comprising desloratadine and a suitable, inert pharmaceutically acceptable carrier or diluent, wherein the method comprises administering the composition once a day for about 10 days, for example, as claimed in independent claim 73. In addition, the claims of Villani, et al. do not recite a method of treating nasal and non-nasal symptoms of seasonal and perennial allergic rhinitis in a human of 12 years and older, for example as set forth in claim 80 of the present application. Nor do the claims of Villani, et al. recite a method of treating symptoms of chronic idiopathic urticaria in a human of 12 years and older, for example as set forth in claim 81 of the present application.

Moreover, Applicants do not find any disclosure in the Villani, et al. patent that discusses the varied features set forth and presently claimed in Applicants' invention. Similarly, the disclosure of neither Hitzig nor Gray provides any of these missing features.

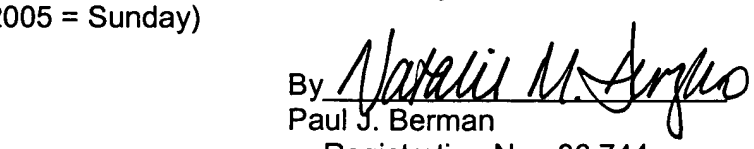
In view of the above, an obviousness-type double patenting rejection over claims 3 and 15 of Villani et al. in view of Hitzig and Gray is not appropriate with respect to the present claims.

* * *

Therefore, Applicants submit each of the currently pending claims in this application has addressed the presently outstanding rejections. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Dated: March 28, 2005
(March 27, 2005 = Sunday)

Respectfully submitted,

By 

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